VALUE ANALYSIS and PRODUCT INFORMATION KIT

New
SHORT WIRE
Delivery System

ConMed

GORE
Authorized Distributor
of Gore Medical Products

GORE VIABIL®
SHORT WIRE
BILIARY ENDOPROSTHESIS

Intended for palliation of malignant strictures in the biliary tree

Table of contents

Product overview

KEY CONSIDERATIONS

GORE® VIABIL® Short Wire Biliary Endoprosthesis is the only fully covered metal stent that has clinical data that demonstrates long term patency and lower risk of migration. Increased patency and reduced migration equals fewer interventions, cost savings, and improved patient quality of life.

The key considerations for your value analysis include:

1. The product:

The GORE® VIABIL® Short Wire Biliary Endoprosthesis is a flexible, self-expanding endoprosthesis providing a means for endoscopically implanting at the target site in the biliary tract. Benefits include:

- **Demonstrated low migration –** Fully covered atraumatic anchoring fins, single continuous nitinol wire design with combination of lowest axial and moderate radial forces[1]
- **Prevents tissue ingrowth –** End-to-end liner constructed from high strength, chemically stable, impermeable ePTFE/FEP provides an absolute permanent barrier
- **Long-term patency –** Permanent, impermeable ePTFE / FEP barrier which prevents tissue ingrowth, and allows for high conformability. Both features reduce premature obstruction.
- **Improved treatment options for hilar strictures –** Optional transmural drainage holes and exclusive 10 cm length permits side branch flow

2. Those who benefit:

- Complex patients at high risk of migration
- Interventional endoscopists providing ERCP w/ metal stent treatment for malignant biliary strictures
- Hospitals offering therapeutic endoscopy services

3. The financial impact:

Anti-migration Assurance Program*

With a 0.2% average reported migration rate, GORE® VIABIL® Short Wire Biliary Endoprosthesis is the only fully covered metal stent with anti-migration technology proven to reduce the risk of reintervention. Gore is so confident in these outcomes, we offer an Anti-migration Assurance program for GORE® VIABIL® Short Wire Biliary Endoprosthesis if a migration occurs.

Additional interventions increase the overall cost to treat:

- The average geometric mean cost of a hospital outpatient ERCP with stent placement for patients without complications is approximately $3,700 (CY2016 Hospital Outpatient Prospective Payment System (OPPS) Final Rule. Centers for Medicare & Medicaid Services Web site. Published November 13, 2015. Accessed December 14, 2016).
- The average cost of a hospital inpatient ERCP with stent placement for patients without complications is approximately $4,649 (National healthcare payer database, 2015)
- Based on migration data, for every 100 patients with stent placement, the use of GORE® VIABIL® Short Wire Biliary Endoprosthesis will potentially eliminate 5 device migrations (as compared to the closest competitive option), which is a savings of at least $23,000 (not including the cost of the stent)

4. Impact on patient outcomes:

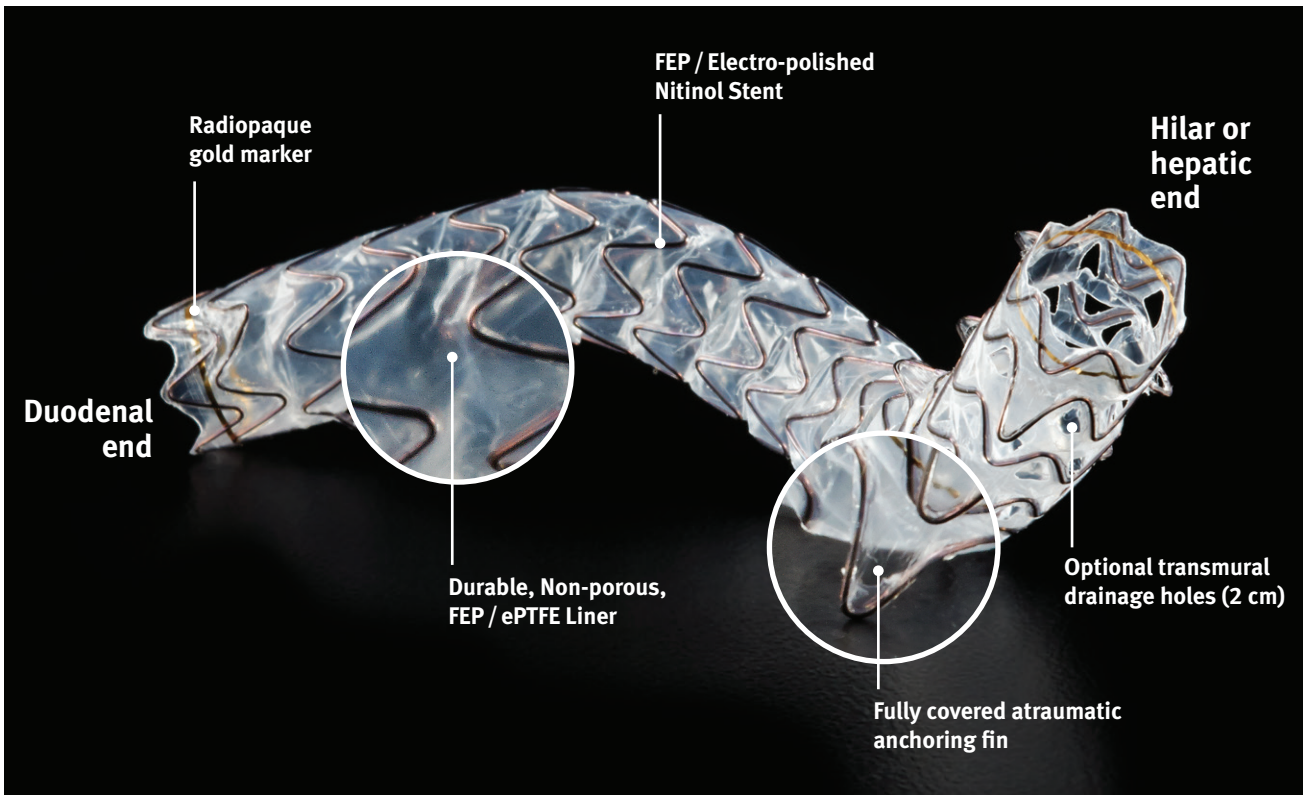
An improved alternative with reduced migrations resulting in minimal reinterventions and better quality of life.

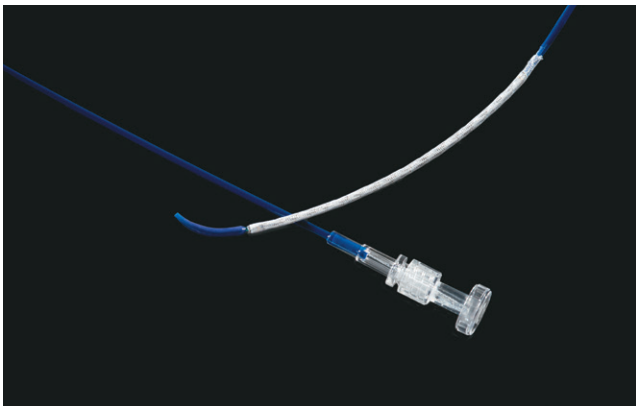
* For full program details refer to Economic Value Analysis Section, sub-section 3.3.

Product overview

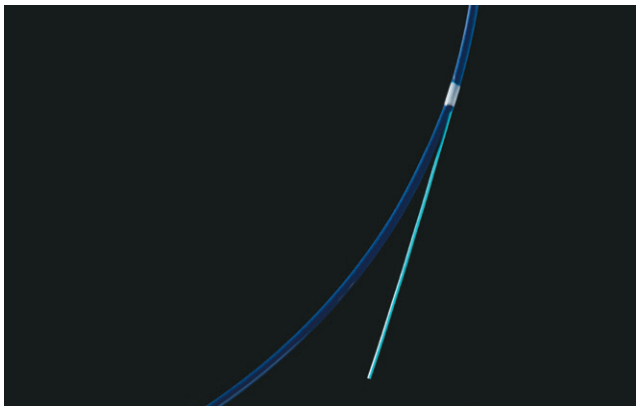
FEATURES AND BENEFITS

GORE® VIABIL® Short Wire Biliary Endoprosthesis is the only fully covered metal stent designed to prevent migrations, demonstrated through supporting clinical data.





Catheter and device



Guidewire exit port

Product overview

To be an effective device for the treatment of a biliary obstruction, precise placement, high patency and low migration are needed. With its unique combination of features and benefits, **GORE® VIABIL® Short Wire Biliary Endoprosthesis is the only fully covered metal stent with anti-migration technology proven to reduce the risk of reintervention.**

Feature	Benefit	Competitive Differentiation
Fully covered atraumatic anchoring fins	Prevents migration	Reported migrations ranging from 0–1.4% compared to migration rates up to 13% for the BOSTON SCIENTIFIC WALLFLEX Biliary RX Fully Covered Stent
Electro-polished Nitinol stent	Moderate radial force and low axial force, which prevents compression and migration	Reported migrations ranging from 0–1.4% compared to migration rates up to 13% for the BOSTON SCIENTIFIC WALLFLEX Biliary RX Fully Covered Stent
A durable, nonporous ePTFE / FEP end-to-end liner	Provides an absolute permanent barrier that prevents tissue ingrowth	Other fully covered metal stents are not completely covered end-to-end, and have liners that are more susceptible to breaking down in the body over time
	Allows for high conformability to reduce premature obstruction for demonstrated long-term patency	• Has the highest long-term patency reported in the literature. • Longer patency = reduced reintervention
Precise delivery system	Non-foreshortening Accurate placement	The only fully covered metal stent that is non-foreshortening Eliminates repositioning associated with typical push-pull delivery systems
Catheter includes a flexible reinforcement wire	Enhanced pushability	Seven out of seven physicians selected GORE® VIABIL® Short Wire Biliary Endoprosthesis as having better pushability when compared to BOSTON SCIENTIFIC WALLFLEX Biliary RX Fully Covered Stent in a simulated stricture model[2]
Optional drainage holes (available on some sizes) and exclusive 10 cm length	Permits side branch flow for improved treatment options of hilar strictures	The only device with optional drainage holes and available in the 10 cm length for this treatment option

Product overview

VALUE PROPOSITION

GORE® VIABIL® Short Wire Biliary Endoprosthesis was designed with one purpose – advance patient care through successful outcomes in the treatment of malignant biliary strictures at high risk of migration. Migration prevention reduces incidents requiring intervention. This provides value for:

Patients:

Sustained long-term patency and reduced migration results in fewer reintervention, keeping the patient out of the hospital and at home with family and friends.

Physicians:

Reduced migration and higher patency leading to reduced reintervention in complex cases.

Hospitals:

Positive clinical outcomes with reduced number of procedures, an increased ability to care for a greater number of total patients, as well as cost savings.

Payers:

An efficient solution in complex malignant cases, minimizes the need for multiple devices per patient and overall cost to treat.

COMPETITIVE
DIFFERENTIATION

Competitive differentiation

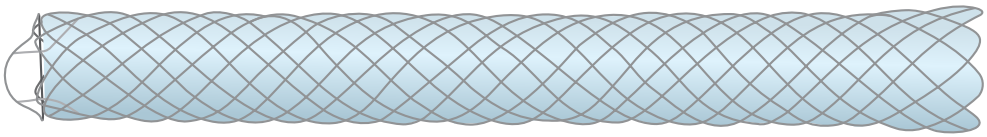
LOWEST MIGRATION RATES

GORE® VIABIL® Short Wire Biliary Endoprosthesis is the only fully covered metal stent designed to minimize migration and has supporting clinical data.

Reduced migration for reduced reintervention.

Reducing reintervention means not having an additional ERCP procedure. An ERCP procedure may be associated with well-known complication rates[3], including pancreatitis (3.5%), hemorrhage (1.3%), perforation (0.1%–0.6%), cholangitis (1% or less), cholecystitis (0.2%–0.5%), cardiopulmonary (1%), and mortality (0.4%–0.5%).

GORE® VIABIL® Short Wire Biliary Endoprosthesis has reported migration rates ranging from 0–1.4% for malignant biliary strictures (with only one migration out of 663 patients reported).[4]

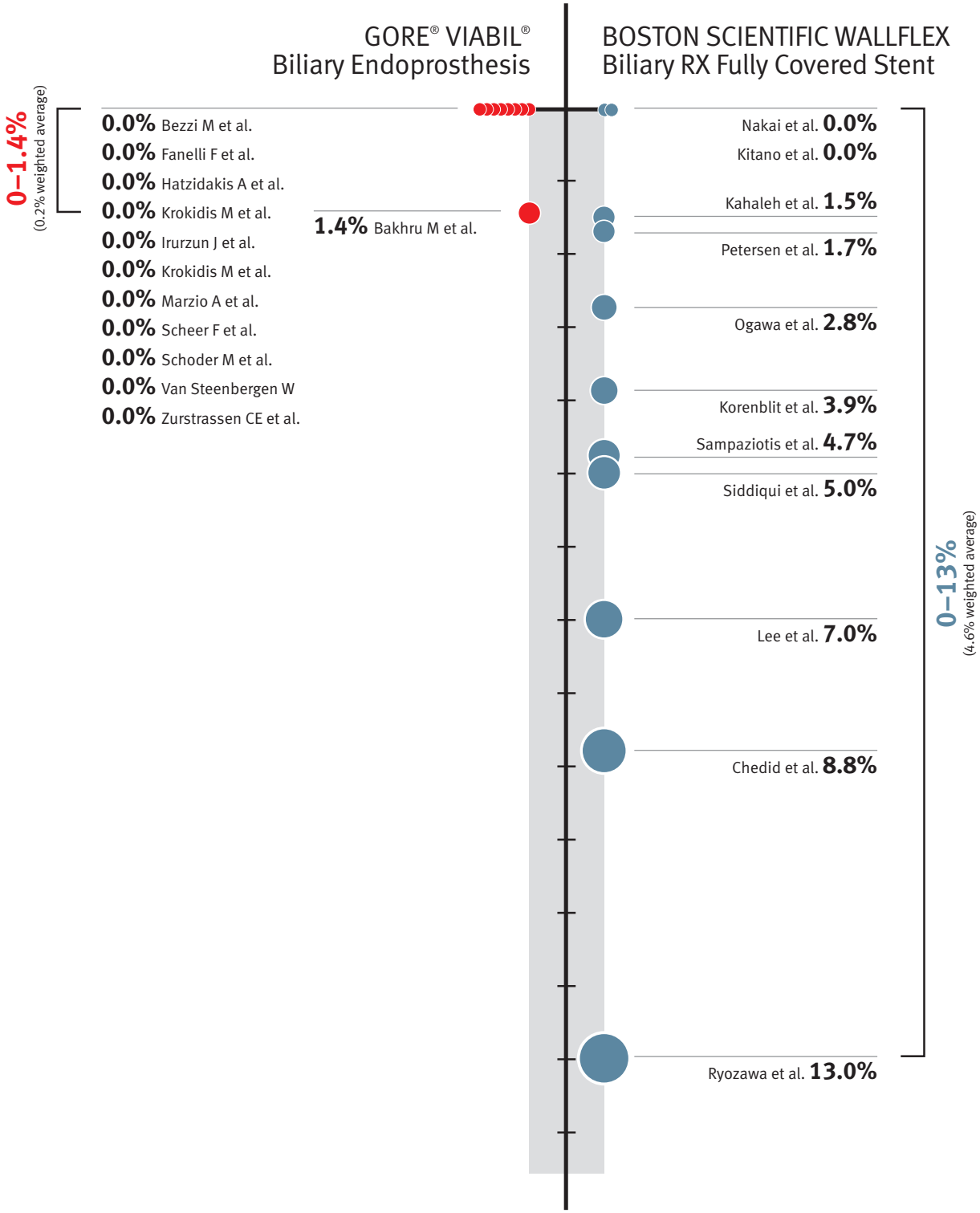


BOSTON SCIENTIFIC WALLFLEX Biliary RX Fully Covered Stent has reported migration rates ranging up to 13%* for malignant biliary strictures.

Competitive differentiation

MIGRATION RATE COMPARISON[4]

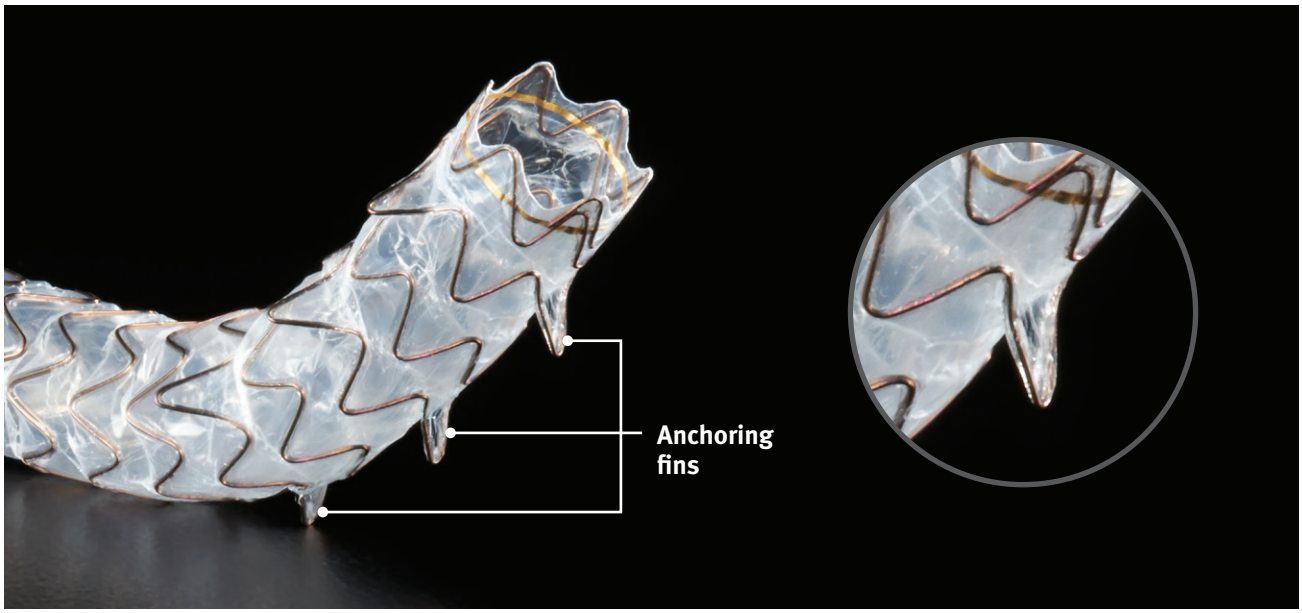
BASED ON 23 PAPERS PUBLISHED FROM 2002 TO 2015.

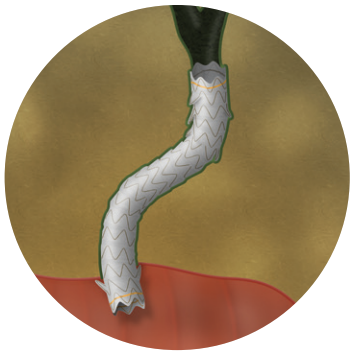


Competitive differentiation

ANCHORING FIN TECHNOLOGY

Fully covered atraumatic anchoring fins





Bile duct conforms to multiple rows of fins anchoring hilar end of device

Single row anchors in duodenum

Competitive differentiation

IMPORTANCE OF AXIAL AND RADIAL FORCES

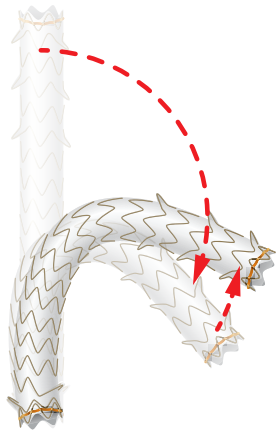
The right fit and flexibility help prevent migration and sludge formation.[3]

The GORE® VIABIL® Short Wire Biliary Endoprosthesis has the preferred balance of moderate Radial force and low Axial force minimizing the risk of migration.[3]

STRAIGHTENING AXIAL FORCE[1,5]

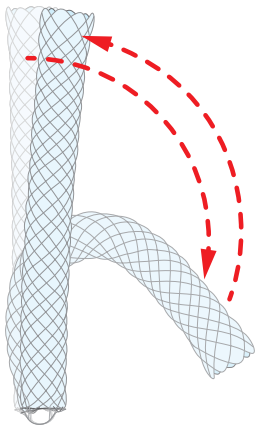
Axial force (Af) =
the recovery force that leads to straightening after being bent.

Low Af



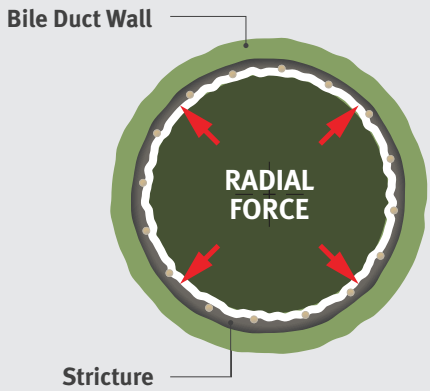
GORE® VIABIL® Short Wire Biliary Endoprosthesis

High Af



BOSTON SCIENTIFIC WALLFLEX Biliary RX Fully Covered Stent

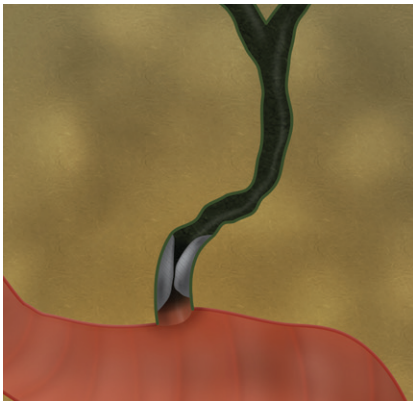
Radial force (Rf) =
maintains and expands the luminal patency at the stricture once deployed.



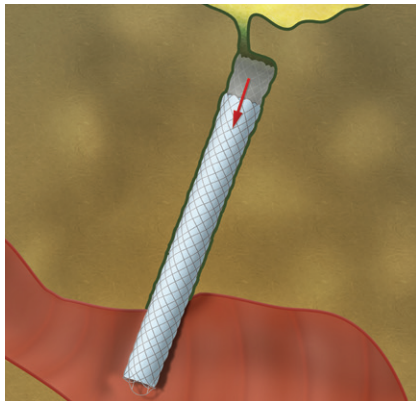
Competitive differentiation

IMPORTANCE OF AXIAL AND RADIAL FORCES

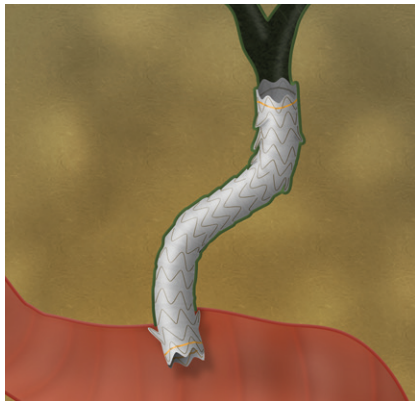
- SEMS with high Af do not conform well in the curved bile duct, which **can increase the risk of stent migration.**[5]
- Additionally, with a high Af, the bile duct tends to kink at the proximal edge of the straightening stent, which causes sludge formation or cholangitis.[5]
- A balance of moderate Rf with low Af is preferred for optimal performance.[3]



Bile duct anatomy



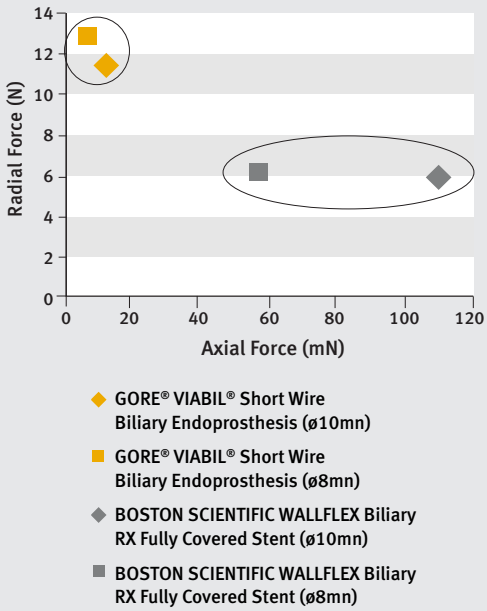
Nonconformable
Other devices can straighten the duct, increasing the risk of kinking, device migration, and premature obstruction



Conformable
GORE® VIABIL® Short Wire Biliary Endoprosthesis device minimizes risk of kinking, device migration, and premature obstruction

Compared to the BOSTON SCIENTIFIC WALLFLEX Biliary RX Fully Covered Stent, the GORE® VIABIL® Short Wire Biliary Endoprosthesis device has low Af and moderate Rf, the preferred combination for reducing migration and achieving higher patency.[3]

- Referencing Isayama's test method, we have characterized and compared the GORE® VIABIL® Short Wire Biliary Endoprosthesis device to BOSTON SCIENTIFIC WALLFLEX Biliary RX Fully Covered Stent
- As shown to the right, GORE® VIABIL® Short Wire Biliary Endoprosthesis device has[1,5]:
  - Approximately twice the Rf and one-tenth the Af compared to the 10 mm BOSTON SCIENTIFIC WALLFLEX Biliary RX Fully Covered Stent
  - The preferred balance of low Af and moderate Rf equaling low migrations

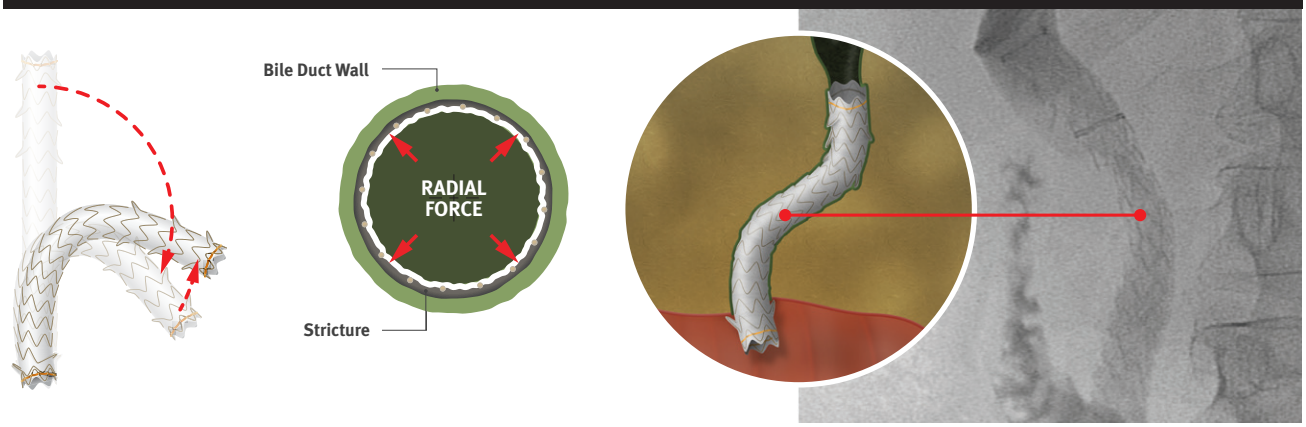


Competitive differentiation

IMPORTANCE OF AXIAL AND RADIAL FORCES

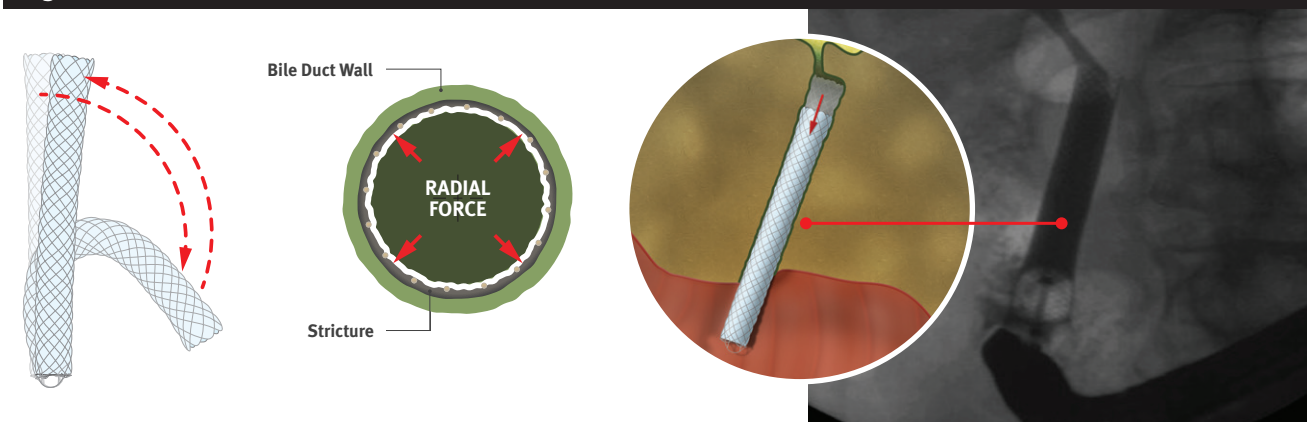
GORE® VIABIL® Short Wire Biliary Endoprosthesis with the preferred balance of low Af and moderate Rf conforms naturally to the bile duct anatomy.[3]

Low Af + Moderate Rf



BOSTON SCIENTIFIC WALLFLEX Biliary RX Fully Covered Stent with a high Af and low Rf straightens the bile duct anatomy, which increases the risk of migration. Additionally, the duct tends to kink at the proximal edge of the stent, causing sludge formation or cholangitis.[6]

High Af + Low Rf



Competitive differentiation

LONG-TERM PATENCY

Proven Highest Patency

Features

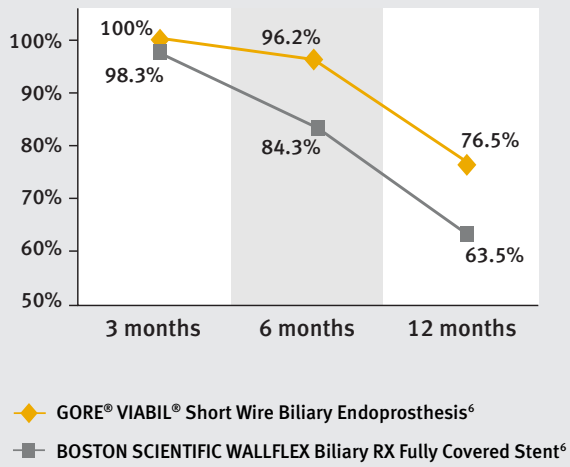
- Durable, non-porous ePTFE / FEP liner
- Prevents tumor ingrowth and tissue attachment
- Minimized acute bacterial attachment
- Preferred balance of moderate radial force + low axial force[7]

Clinical Benefit

- Improved long-term patency
- Improved quality of life

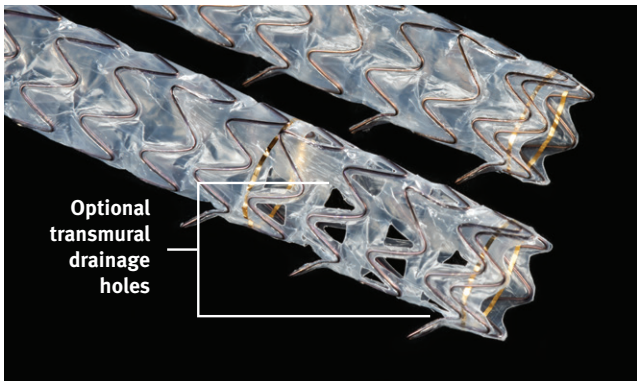
Clinical performance demonstrates **GORE® VIABIL® Short Wire Biliary Endoprosthesis maintains higher primary patency than the leading competitor at 3, 6, and 12-months.**[8,9] Improved long-term patency can mean an improved quality of life for patients.

Higher Primary Patency



Improved treatment of hilar strictures

- Optional transmural drainage holes and exclusive 10 cm length permits side branch flow for improved treatment options for hilar strictures



Competitive differentiation

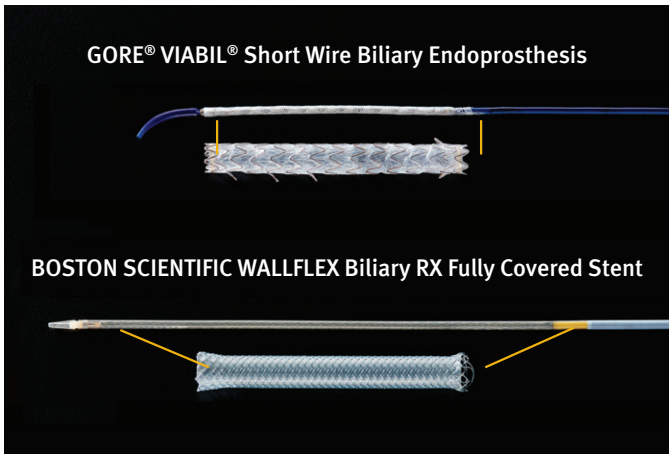
NON-FORESHORTENING

GORE® VIABIL® Short Wire Biliary Endoprosthesis non-foreshortening endoprosthesis design*

- Enables precise positioning and deployment
- Stent will not change length over time

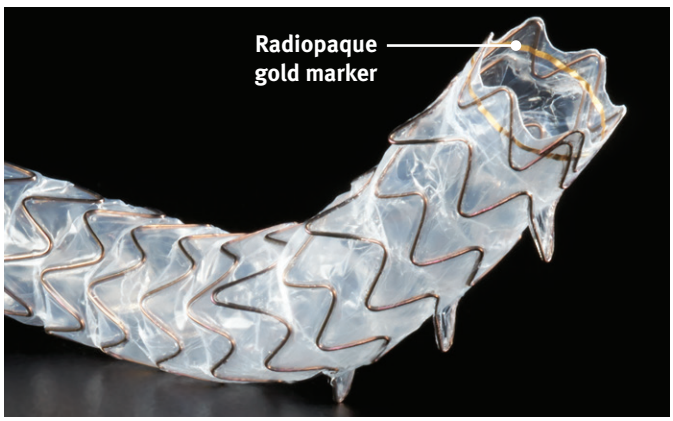
Foreshortening concerns with other devices

- Can decrease physician confidence
  - Challenging to place accurately
  - Stent can shorten over time, compromising effectiveness
  - Complexity and challenging to maintain accuracy, coordinated effort, requires additional effort
  - Eliminates repositioning associated with typical push / pull delivery



Radiopaque Markers

- Placed at the leading end of the outer sheath and the leading tip of the inner catheter, enable easy visualization and accurate placement

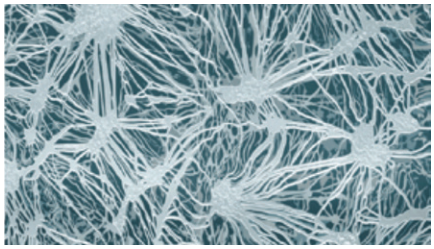


* If used as directed the product with not appreciably foreshorten

Competitive differentiation

ePTFE MATERIAL

- Permanent ePTFE tissue barrier prevents tumor ingrowth and tissue attachment leading to improved patency
- Gore is the world leader in understanding and engineering PTFE, expanded PTFE, and PTFE composites into thousands of varied products
- In the last ten years, more than 700,000 Gore ePTFE stent grafts have been implanted worldwide

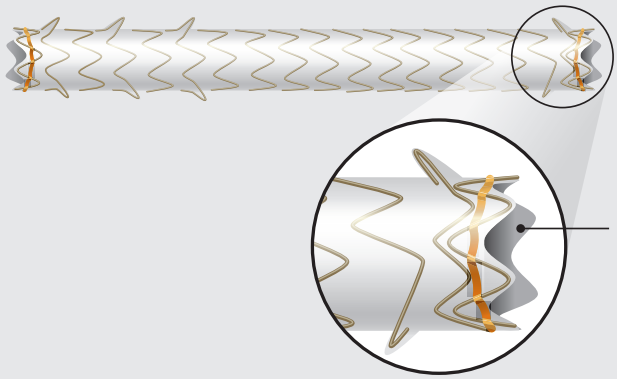


This micrograph of expanded PTFE material (ePTFE) was shot with a magnification of 40,000x

PREVENTION OF TISSUE INGROWTH

GORE® VIABIL® Short Wire Biliary Endoprosthesis

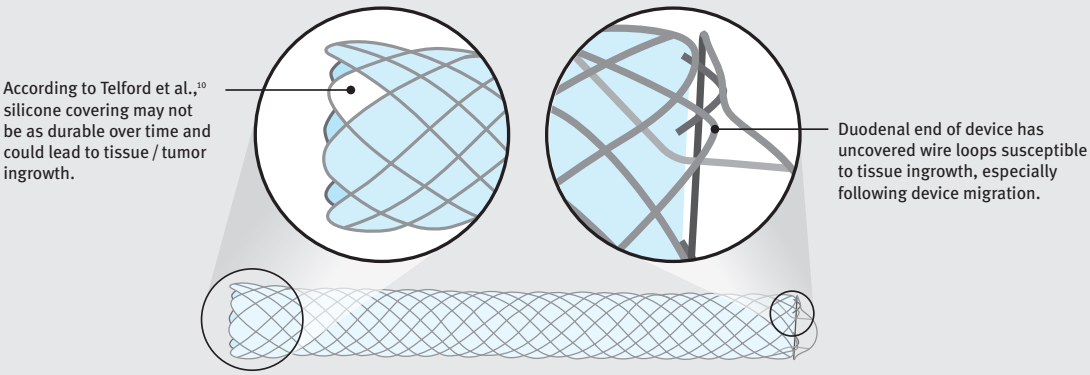
- End to end ePTFE covering.
- PTFE cannot chemically degrade in the body.
  - No human explant has ever been reported showing changes in Gore's PTFE properties in the body over time.



The end-to-end liner of the GORE® VIABIL® Short Wire Biliary Endoprosthesis is constructed from high strength, chemically stable, impermeable ePTFE / FEP that provides an absolute permanent barrier that **prevents tissue ingrowth**.

BOSTON SCIENTIFIC WALLFLEX Biliary RX Fully Covered Stent

- Silicone covering, ends uncovered. Silicone covering has been shown to fail to prevent tissue / tumor ingrowth in clinical studies.[10] There have been no reports of tissue/tumor ingrowth with ePTFE coverings.



According to Telford et al.,[10] silicone covering may not be as durable over time and could lead to tissue / tumor ingrowth.

Duodenal end of device has uncovered wire loops susceptible to tissue ingrowth, especially following device migration.

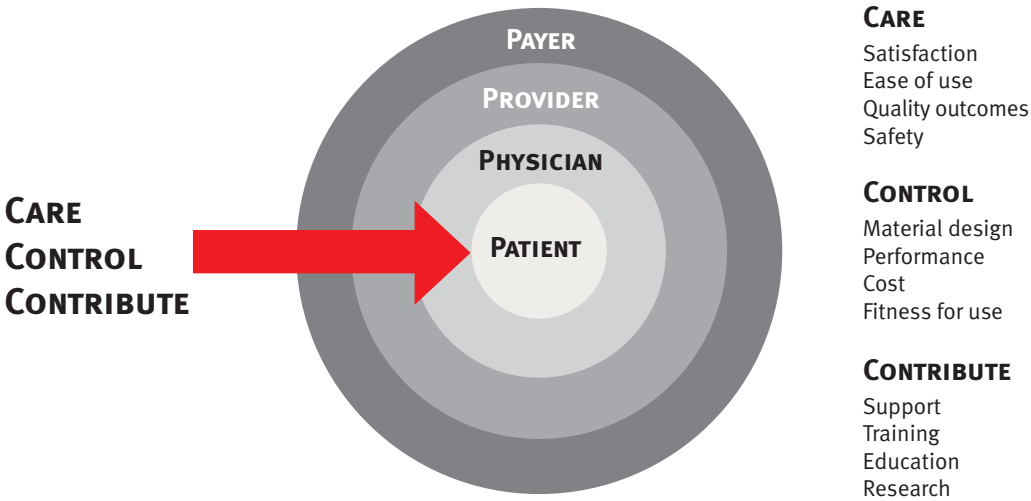
VALUE ANALYSIS

Value analysis

OVERVIEW

Healthcare professionals understand that in order to deliver the best patient care possible, they will need to operate beyond the intersection of cost, quality, and outcomes. When choosing products for a hospital system, the focus is changing from "cost of product" to "cost of care." The cost of care extends well beyond surgery, to include follow-up care, procedures, a return to the patient's previous activities, and quality of life.

Our analysis of value covers those comprehensive, multi-dimensional factors that we can control, thus providing us with the ability to work with healthcare providers in delivering the greatest impact and value in patient care.



Patients:
Sustained long-term patency and reduced migration results in fewer reintervention, keeping the patient out of the hospital and at home with family and friends.

Physicians:
Reduced migration and higher patency leading to reduced reintervention in complex cases.

Hospitals:
Positive clinical outcomes with reduced number of procedures, an increased ability to care for a greater number of total patients, as well as cost savings.

Payers:
An efficient solution in complex malignant cases, minimizes the need for multiple devices per patient and overall cost to treat.

An additional intervention is an additional ERCP procedure and includes risks.

- An ERCP procedure may be associated with well-known complication rates[7], including pancreatitis (3.5%), hemorrhage (1.3%), perforation (0.1%–0.6%), cholangitis (1% or less), cholecystitis (0.2%–0.5%), cardiopulmonary (1%), and mortality (0.4%–0.5%)

Value analysis

ECONOMIC VALUE ANALYSIS

The financial impact

For each migration the patient must undergo a new intervention for additional stent placement. **BOSTON SCIENTIFIC WALLFLEX Biliary RX Fully Covered Stent has reported up to 13% migration rate (n=156), with typical ERCP interventions costing $3,700**, this can end up costing the hospital significantly.

In comparison, **GORE® VIABIL® Biliary Endoprosthesis only has one reported migration out of 448 patients** reported in the literature. Migration as well as lack of patency require additional intervention, resulting in additional hospital stays and increased hospital costs.

Migration leads to unplanned reintervention

An unplanned intervention has negative consequences:

- Increases overall cost to treat:
  - The average geometric mean cost of a **hospital outpatient** ERCP with stent placement for patients without complications is **approximately $3,700** (CY2016 Hospital Outpatient Prospective Payment System (OPPS) Final Rule. Centers for Medicare & Medicaid Services Web site. Published November 13, 2015. Accessed December 14, 2016)
  - The average cost of a **hospital inpatient** ERCP with stent placement for patients without complications is **approximately $4,649** (National healthcare payer database, 2015)
- Decreased organizational effectiveness[11]

Assume your hospital does 100 ERCP with stent placements per year, with the average patient survival for malignant strictures being 6 months.

	GORE® VIABIL® Short Wire Biliary Endoprosthesis	BOSTON SCIENTIFIC WALLFLEX Biliary RX Fully Covered Stent
Migration Rate (average)[9]	0.2%	4.6%
Estimated number of reinterventions to manage migrations (per year)	1	5
Estimated patency at 6 months[6,8]	96.2%	84.3%
Estimated number of reinterventions to manage loss of patency (per year)	4	16
Total number of reinterventions expected per year	5	21
Estimated additional cost per year due to reinterventions (includes ERCP + Stent cost)	**$32,205**	**$151,221**

Potential economic impact

If GORE® VIABIL® Short Wire Biliary Endoprosthesis was used to treat 100 patients with unresectable malignant biliary strictures, your institution is estimated to annually:

Eliminate 16 reinterventions due to migrations and reduced patency and **save $116,716** versus using BOSTON SCIENTIFIC WALLFLEX Biliary RX Fully Covered Stent.

Value analysis

ANTI-MIGRATION ASSURANCE PROGRAM

Migrations are a known risk for any biliary endoprosthesis. With a 0.2% average reported migration rate, GORE® VIABIL® Short Wire Biliary Endoprosthesis is the only fully covered metal stent with anti-migration technology proven to reduce the risk of reintervention. Gore is so confident in these outcomes, we are now offering a Device Replacement program for GORE® VIABIL® Short Wire Biliary Endoprosthesis if a migration occurs.

Program Details

Gore will provide a replacement device of identical dimensions for use with the patient whose device migrates within one year post implantation. The replacement device is only available if GORE® VIABIL® Short Wire Biliary Endoprosthesis is implanted in accordance with the device *Instructions for Use* (The GORE® VIABIL® Short Wire Biliary Endoprosthesis is intended for palliation of malignant strictures in the biliary tree) and the other terms of the program are satisfied. Replacement devices provided under this program are not eligible for the program. Claims under the program are limited to the replacement device. Upon receipt of the appropriate documentation, a replacement device will be provided pursuant to the program accompanied by a no-charge invoice shipped directly to the hospital. The hospital is responsible for reporting the no-charge replacement stent as a discount on the hospital's cost report. All reports of migration will be documented appropriately within the Gore internal product surveillance process and additional information may be requested. Migrations are a known risk of any biliary endoprosthesis. The provision of a replacement device as part of the program does not constitute an admission that there was a device malfunction or defect or that Gore, its employees or agents, or the Gore device caused or contributed to any complications or injuries. Please see the device *Instructions for Use* for further information on the device contraindications, warnings, precautions, and potential adverse events. The program is subject to modification or termination by W. L. Gore & Associates without prior notification and this program is only applicable for the United States.

Value analysis

RANDOMIZED PROSPECTIVE CLINICAL DATA – REPRESENTATIVE STUDY

Percutaneous Palliation of Pancreatic Head Cancer: Randomized Comparison of ePTFE / FEP-Covered Versus Uncovered Nitinol Biliary Stents

Krokidis M, Fanelli F, Orgera G, Tsetis D, Mouzas M, Bezzi M, Kouroumalis E, Pasariello R, Hatzidakis A, 2011[7]

Device	Patients	Technical Success	Lifetime Paliation	Primary Patency (days)	Percent Primary Patency[7] 3 Months	6 Months	12 Months
GORE® VIABIL® Biliary Endoprosthesis	n=40	100%	90% (36 / 40)	Mean 234	97.3%	92.2%	87.6%
BARD® LUMINEXX® Biliary Stent	n=40	100%	70% (28 / 40)	Mean 166	77.5%	69.8%	69.8%

Dysfunctions (e.g. tumor overgrowth)	Time to Reintervention (days)	Migration	Cholecystitis	Pancreatitis
10% (4/40)*	Mean 126.5	0 / 40	0 / 40	0 / 40
30% (12/40)	Mean 82.9	0 / 40	0 / 40	0 / 40

*$p < 0.05$

Study Details

- Design: multicenter, prospective, randomized
- Purpose: compare clinical effectiveness of covered GORE® VIABIL® Biliary Endoprosthesis stents (n = 40) to uncovered metallic BARD® LUMINEXX® Biliary Stent (n = 40)
- Etiology: 80 pancreatic adenocarcinoma
- Inclusion: obstructive jaundice caused by unresectable pancreatic head adenocarcinoma, which in turn caused occlusion of the biliary tree at the lower half of the common bile duct
- Exclusion: three of six of the following: total serum bilirubin level ≥15 mg / dl, leukocytosis ≥11 x 10^9/ l, gamma glutamil transferase (yGT) >165 IU / l, prothrombin ratio ≥1.4, C-reactive protein (CRP) ≥5 mg/dl, and serum carbohydrate antigen 19-9 (CA 19-9)level ≥10.000 IU/ml
- Survival / Implant Duration / Follow-up:
  – GORE® VIABIL® Biliary Endoprosthesis: ~8.1months (mo): median 247days (d)
  – BARD® LUMINEXX® Biliary Stent: ~6.7mo: median 203d
- Complications:
  – GORE® VIABIL® Biliary Endoprosthesis: 12.5% (5 / 40) - 3 peritoneal irritation, 2 self limited biliary hemorrhage
  – BARD® LUMINEXX® Biliary Stent: 10% (4 / 40) – 2 peritoneal irritation, 2 self limited biliary hemorrhage

Conclusions

"Regarding primary patency and ingrowth rate, ePTFE / FEP-covered stents [GORE® VIABIL® Biliary Endoprosthesis] have shown to be significantly superior to bare nitinol stents for the palliation of malignant jaundice caused by inoperable pancreatic head cancer and pose comparable cost and complications."

"Use of a covered stent does not significantly influence overall survival rate; nevertheless, the covered endoprosthesis seems to offer result in fewer reinterventions and better quality of patient life."

RANDOMIZED PROSPECTIVE CLINICAL DATA – REPRESENTATIVE STUDY

Percutaneous Treatment of Malignant Jaundice Due to Extrahepatic Cholangiocarcinoma: Covered Viabil [GORE® VIABIL® Biliary Endoprosthesis] Stent Versus Uncovered BOSTON SCIENTIFIC WALLSTENT Endoprosthesis

Krokidis M, Fanelli F, Orgera G, Bezzi M, Passariello R, Hatzidakis A, 2010[3]

					Percent Primary Patency[7]		
Device	Patients	Technical Success	Lifetime Paliation	Primary Patency (days)	3 Months	6 Months	12 Months
GORE® VIABIL® Biliary Endoprosthesis	n=30	100%	87% (26 / 30)	Mean 227.3	NA	NA	NA
BOSTON SCIENTIFIC WALLSTENT Endoprosthesis	n=30	100%	70% (21 / 30)	Mean 166.0	NA	NA	NA

Dysfunctions (e.g. tumor overgrowth)	Time to Reintervention (days)	Migration	Cholecystitis	Pancreatitis
13.3% (4 / 30)*	Mean 179.5*	0 / 30	0 / 30	0 / 30
30% (9 / 30)	Mean 133.1	0 / 30	0 / 30	0 / 30

*$p < 0.05$

Study Details

- Design: multicenter, prospective, randomized
- Purpose: compare the clinical results of GORE® VIABIL® Biliary Endoprosthesis (n = 30) stent grafts versus BOSTON SCIENTIFIC WALLSTENT Endoprosthesis (n = 30)
- Etiology: 80 unresectable extrahepatic cholangiocarcinoma
- Inclusion: Bismuth type I unresectable extrahepatic cholangiocarcinoma, with a total serum bilirubin level <15 mg/dl, absence of hepatic metastasis, patient age ≤ 80 years, a satisfactory coagulation status (INR value ≤ 1.5 and platelet count value of ≥70,000), and a performance status >3 on the Eastern Cooperative Oncology Group scale
- Exclusion: intrahepatic and hepatic bifurcation (Klatskin) tumors, presence of hepatic metastasis, patient age [80 years, previous surgical or radiotherapeutical palliative treatment, and very poor patient general condition]
- Survival / Implant Duration / Follow-up:
  - GORE® VIABIL® Biliary Endoprosthesis: ~8.0mo: median 243.5d
  - BOSTON SCIENTIFIC WALLSTENT Endoprosthesis: ~5.9mo: median 180.5
- Complications:
  - GORE® VIABIL® Biliary Endoprosthesis: 10% (3 / 30) – 2 peritoneal irritation, 1 biloma formation
  - BOSTON SCIENTIFIC WALLSTENT Endoprosthesis: 13.3% (4 / 30) – 3 peritoneal irritation, 1 self limited biliary hemorrhage

Conclusions

"In conclusion, Viabil [GORE® VIABIL® Biliary Endoprosthesis] stents have been shown to be safe for palliation of malignant jaundice caused by extrahepatic cholangiocarcinoma. They also seem to be effective in preventing tumor ingrowth and may therefore reduce the rate of stent occlusion and increase patients' quality of life."

"The results of this study suggest that Viabil [GORE® VIABIL® Biliary Endoprosthesis] stents may be superior to conventional uncovered BOSTON SCIENTIFIC WALLSTENT Endoprosthesis in the management of malignant biliary obstruction due to Bismuth type I cholangio-carcinoma, with similar costs and complication rates, and, therefore, should be considered as the first option in the selection of an endoprosthesis, especially for inoperable patients in relatively good general condition."

PRODUCT USE RECOMMENDATIONS

Product use recommendations

GORE® VIABIL® Short Wire Biliary Endoprosthesis is the only fully covered metal stent with anti-migration technology proven to reduce the risk of reintervention. The GORE® VIABIL® Short Wire Biliary Endoprosthesis is intended for palliation of malignant strictures in the biliary tree.

Refer to *Instructions for Use* for a complete description of all warnings, precautions, and contraindications.

Product Replacement

Fully covered self-expanding metal stents product availability

Size (diameter x length)	GORE® VIABIL® Short Wire Biliary Endoprosthesis	Boston Scientific WALLFLEX Biliary RX Fully Covered Stent
8 mm x 40 mm	VSWVN0804	—
8 mm x 60 mm	VSWVN0806	M00570500
8 mm x 80 mm	VSWVN0808	M00570510
8 mm x 100 mm	VSWVN0810	—
10 mm x 40 mm	VSWVN1004	M00570520
10 mm x 60 mm	VSWVN1006	M00570530
10 mm x 80 mm	VSWVN1008	M00570540
10 mm x 100 mm	VSWVN1010	—
8 mm x 60 mm with drainage holes	VSWVH0806	—
8 mm x 80 mm with drainage holes	VSWVH0808	—
8 mm x 10 mm with drainage holes	VSWVH0810	—
10 mm x 60 mm with drainage holes	VSWVH1006	—
10 mm x 80 mm with drainage holes	VSWVH1008	—
10 mm x 100 mm with drainage holes	VSWVH1010	—

Materials management information

CATALOGUE NUMBERS

Endoscopic

Catalogue Number	Endoprosthesis Diameter (mm) × Length (cm)	Working Length of Delivery Catheter (cm)	Drainage Holes Located At the Hilar Region	Transmural Drainage Holes Length (cm)
VSWVN0804	8 x 4	200	No holes	—
VSWVN0806	8 x 6	200	No holes	—
VSWVN0808	8 x 8	200	No holes	—
VSWVN0810	8 x 10	200	No holes	—
VSWVN1004	10 x 4	200	No holes	—
VSWVN1006	10 x 6	200	No holes	—
VSWVN1008	10 x 8	200	No holes	—
VSWVN1010	10 x 10	200	No holes	—
VSWVH0806	8 x 6	200	Holes	2
VSWVH0808	8 x 8	200	Holes	2
VSWVH0810	8 x 10	200	Holes	2
VSWVH1006	10 x 6	200	Holes	2
VSWVH1008	10 x 8	200	Holes	2
VSWVH1010	10 x 10	200	Holes	2

Sizing, availability and pricing varies by country.
Please check with your Gore representative for availability.

INSTRUCTIONS FOR USE

GORE® VIABIL® Short Wire Biliary Endoprosthesis

For Endoscopic Delivery

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

DESCRIPTION

The GORE® VIABIL® Short Wire Biliary Endoprosthesis is a flexible, self-expanding endoprosthesis that is compressed and secured onto the distal end of a delivery catheter. The catheter provides a means for endoscopically implanting the GORE® VIABIL® Short Wire Biliary Endoprosthesis at the target site in the biliary tract.

The endoprosthesis consists of an expanded polytetrafluoroethylene (ePTFE) and fluorinated ethylene propylene (FEP) tubular lining that is externally supported along its length by a Nitinol stent and incorporates radiopaque rings at both ends **(Figure 1)**. Covered anchoring fins are incorporated into the Nitinol stent to reduce the risk of endoprosthesis migration.

Some sizes of the GORE® VIABIL® Short Wire Biliary Endoprosthesis are available with transmural drainage holes in the lining for 2 cm along the hepatic end of the endoprosthesis **(Figure 2)**. These holes are triangular in shape and are intended to allow for endoprosthesis placement across a branch duct under appropriate anatomical circumstances. A third radiopaque ring is present on endoprostheses with transmural drainage holes to fluoroscopically identify the boundaries of the holed region.

For endoscopic delivery, the delivery system consists of a 200 cm length, 8.5 Fr diameter, dual lumen catheter, hub, deployment knob and line. The dual lumen catheter shaft connects a curved tapered tip and distal end of the delivery catheter with constrained endoprosthesis to a catheter hub that allows deployment line withdrawal. The endoprosthesis is constrained on the distal end of the delivery catheter inside a double layer of line. One lumen of the catheter shaft allows passage of a 0.035" diameter guidewire from the curved tapered tip through the distal end of the delivery catheter and out a guidewire exit port, which is marked with a white indicator band. The second lumen traverses the entire length of the dual lumen catheter shaft and accommodates the deployment line. To facilitate accurate endoscopic endoprosthesis placement, radiopaque markers are present on the distal and proximal ends of the endoprosthesis **(Figure 3)**.

ENDOPROSTHESIS SIZING METHOD

Endoscopic retrograde cholangiopancreatography (ERCP) should be performed prior to placement of the GORE® VIABIL® Short Wire Biliary Endoprosthesis to characterize the biliary tract morphology and extent of the malignant disease. ERCP should be used to determine the proper diameter and length of the GORE® VIABIL® Short Wire Biliary Endoprosthesis needed for treatment **(Table 1)**.

The GORE® VIABIL® Short Wire Biliary Endoprosthesis should extend at least 2 cm proximal and distal to the margins of the stricture. Positioning should not result in excessive length into the duodenum, approximately 1 cm is recommended. A guidewire with radiopaque markers at known intervals can be used to assist in these measurements. Mapping out the biliary tract cholangiographically is also necessary to determine whether a branch duct may be excluded by placement of the endoprosthesis. Based on the likelihood of excluding a branch duct, a GORE® VIABIL® Short Wire Biliary Endoprosthesis with transmural drainage holes may be selected to decrease the probability of branch duct exclusion. Delivery of the endoprosthesis should be performed using endoscopic and fluoroscopic guidance, and proper placement and patency should be confirmed using cholangiography immediately following deployment.

TABLE 1: ENDOPROSTHESIS SIZING TABLE

Nominal Endoprosthesis Diameter (mm)[1]	Recommended Duct Diameter (mm)[2]	Nominal Endoprosthesis Lengths (cm)[3,4]	Profile of Delivery Catheter (Fr)	Working Lengths of Delivery Catheter (cm)
8	5.5 – 6.9	4 / 6 / 8 / 10	8.5	200
10	7.0 – 9.0	4 / 6 / 8 / 10	8.5	200

1. The outwardly directed covered anchoring fins extend slightly beyond the nominal diameter of the endoprosthesis.
2. The recommended duct diameters are based on a 10 – 30% oversizing.
3. The 4, 6, 8, and 10 cm endoprostheses are available with lining along the entire length of the endoprosthesis. The 6, 8 and 10 cm endoprostheses are also available with transmural drainage holes in the lining for 2 cm along the hepatic end of the endoprosthesis.
4. This represents the nominal undeployed and deployed length of the endoprosthesis. If the device is deployed as instructed, the endoprosthesis will not appreciably foreshorten.

INDICATIONS

The GORE® VIABIL® Short Wire Biliary Endoprosthesis is intended for palliation of malignant strictures in the biliary tree.

CONTRAINDICATIONS

The GORE® VIABIL® Short Wire Biliary Endoprosthesis is contraindicated for:
- ALL CARDIOVASCULAR APPLICATIONS.
- Ducts less than 5.5 mm in diameter or greater than 9 mm in diameter.

INSTRUCTIONS FOR USE *(continued)*

PACKAGE HANDLING

Store in a cool dry place. This product has an expiration date and should be used before the labeled "use by" (expiration) date marked on the box.

WARNINGS

- The safety and effectiveness of this device for use in the vascular system has not been established.
- The GORE® VIABIL® Short Wire Biliary Endoprosthesis should not be cut prior to use and should only be implanted using the catheter system supplied with the endoprosthesis.
- The GORE® VIABIL® Short Wire Biliary Endoprosthesis cannot be recaptured once deployment is initiated and cannot be repositioned once deployment is complete.
- Endoprosthesis placement resulting in excessive length of the endoprosthesis protruding into the duodenum may obstruct the intestinal tract.
- Placement of a fully lined endoprosthesis (without holes) across a branch duct or major bifurcation may result in complications due to blockage of flow from the branch duct and prevent endoscopic or transhepatic access for future procedures.
- Physicians should carefully consider the decision to implant the GORE® VIABIL® Short Wire Biliary Endoprosthesis in patients with active infections or other co-morbidities involving the hepatobiliary system. Physicians should also consider the standard precautions associated with the endoscopic transpapillary manipulation of an 8.5 Fr catheter.
- This product is not intended for removability, and is considered a permanent implant. Specifically, removal of the stent may be impeded by tissue/tumor ingrowth if the stent has transmural drainage holes. In addition, if the stent were placed through a previously placed open cell bare metal stent, removal may be impeded by the structure of the open cell bare metal stent.

PRECAUTIONS

- The GORE® VIABIL® Short Wire Biliary Endoprosthesis is designed for single use only; do not reuse device. Gore does not have data regarding reuse of this device. Reuse may cause device failure or procedural complications including device damage, compromised device biocompatibility, and device contamination. Reuse may result in infection, serious injury, or patient death.
- The GORE® VIABIL® Short Wire Biliary Endoprosthesis should be carefully inspected prior to use to verify that the sterile package has not been damaged and that the appropriate endoprosthesis size has been selected.
- The GORE® VIABIL® Short Wire Biliary Endoprosthesis should only be used by physicians trained in endoscopic techniques.
- Catheter manipulation in the body should only be performed using high quality fluoroscopic equipment and high quality endoscopic equipment.
- Care should be taken to ensure that an endoscope with the appropriate channel size is used prior to advancing the delivery catheter into the body.

MRI SAFETY AND COMPATIBILITY

Non-clinical testing has demonstrated that the GORE® VIABIL® Short Wire Biliary Endoprosthesis is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 and 3.0 Tesla
- Maximum spatial gradient of 3,000 Gauss/cm
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Mode)

Under the scan conditions defined above, the GORE® VIABIL® Short Wire Biliary Endoprosthesis is expected to produce a maximum temperature rise of less than 5.79°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends up to approximately 5 mm from the GORE® VIABIL® Short Wire Biliary Endoprosthesis when imaged with a spin echo or gradient echo sequence a 3.0T MRI system. The artifact does obscure the device lumen.

INSTRUCTIONS FOR USE *(continued)*

HAZARDS AND ADVERSE EVENTS

Complications associated with the use of the GORE® VIABIL® Short Wire Biliary Endoprosthesis may include complications associated with other biliary endoprostheses, including but not limited to: endoprosthesis misplacement, endoprosthesis migration, endoprosthesis fracture, obstruction of branch ducts, bleeding due to vascular erosion, and endoprosthesis occlusion due to biofilm / sludge formation, extrinsic compression or tumor overgrowth at the endoprosthesis ends.

Complications may also include those often associated with any endoscopic procedure performed on the biliary tract. These complications include: infection, bleeding, duct perforation, hematoma, hemobilia, cholangitis, pancreatitis, fever, trauma to ductal system or duodenum, and death.

DIRECTIONS FOR USE — I. ENDOSCOPIC DELIVERY (200 cm CATHETER)

Materials Required for Endoprosthesis Placement

- GORE® VIABIL® Short Wire Biliary Endoprosthesis
- Duodenoscope with 4.2 mm working channel
- 0.035" (0.89 mm) guidewire at least 260 cm long (preferably stiff or extra stiff)
- Appropriate diagnostic catheters, dilators, sphincterotomes and accessories
- Radiopaque contrast solution

A. Endoscopic Retrograde Cholangiopancreatography (ERCP)

1. The distal end of the endoscope is positioned in the duodenum near the location of the major duodenal papilla (papilla of Vater), and the common bile duct (CBD) is cannulated. A sphincterotomy is not always necessary for delivery of the endoprosthesis, but may be performed at the discretion of the implanting physician.
2. Through the injection of contrast solution, define the anatomy of the patient's biliary tract.
3. Through the use of various guidewires, catheters and dilators, place a 0.035" (0.89 mm) guidewire across the biliary stricture. Pre-dilatation of the stricture may be performed at the discretion of the implanting physician.
4. Using the cholangiographic maps of the biliary system, select the appropriate length and diameter GORE® VIABIL® Short Wire Biliary Endoprosthesis to use. An endoprosthesis with transmural drainage holes may be selected if it is necessary to place the endoprosthesis across branch ducts or a bifurcation.

B. Preparation of Endoprosthesis and Deployment Catheter

1. Prior to Opening Sterile Package:
   Check that the endoprosthesis diameter, endoprosthesis length and catheter length are appropriate for the specific procedure before removing it from the packaging. It is recommended that the endoprosthesis extend at least 2 cm past the margins of stricture and that the diameter is slightly oversized **(see Table 1)**. However, if the stricture is located in close proximity to the major duodenal papilla (papilla of Vater), care should be taken to prevent excessive endoprosthesis length from extending into the duodenum (approximately 1 cm is recommended). Ensure that the selected endoprosthesis does not have transmural drainage holes in the lining component unless they are specifically desired.
2. Opening the Sterile Package:
   Carefully inspect the packaging for damage to the sterile barrier. Peel back the outer pouch and remove the coil. Remove the delivery catheter (containing the pre-mounted endoprosthesis) from the coil by grasping the knob and gently pulling to release the hub from the connector tubing (ensure the knob is not twisted as it is removed from the connector tubing). Continue pulling until the entire device has been removed from the coil.
3. Inspection Prior to Use:
   Prior to using the GORE® VIABIL® Short Wire Biliary Endoprosthesis, all materials to be used for the procedure should be carefully examined for bends, kinks, breaks or other damage. Do not use any defective materials.

INSTRUCTIONS FOR USE *(continued)*

C. Introduction of the Delivery System and Deployment of the Endoprosthesis

1. With the endoscope appropriately positioned in the duodenum, ensure that an 0.035" (0.89 mm) diameter "stiff" guidewire with a length of at least 260 cm is in place and lock guidewire in place. **Note:** Never attempt to endoscopically deploy a GORE® VIABIL® Short Wire Biliary Endoprosthesis unless placed over an appropriate guidewire.
2. While holding the delivery system straight, insert the guidewire into the tip of the delivery system while supporting the delivery catheter and the compressed endoprosthesis. Carefully advance the endoprosthesis in small increments (approximately 0.5 cm) until the guidewire exits the exit port marked by the white band near the distal end of the catheter (approximately 30 cm from the tip of the device, distance depends on endoprosthesis size). The guidewire then lies along the side of the delivery system. Continue advancing the delivery system over the guidewire and unlock the wire to pass the delivery system into the endoscope working channel. Lock the guidewire and continue to advance the device through the endoscope working channel, and into the biliary papilla.
   Note: If excessive resistance is felt as the GORE® VIABIL® Short Wire Biliary Endoprosthesis is introduced into the endoscope, remove and inspect the delivery system for damage. Do not reuse the GORE® VIABIL® Short Wire Biliary Endoprosthesis if damaged. Ensure a compatible endoscope working channel size (see Materials Required section), and that the guidewire is free of kinks.
3. Using fluoroscopic and endoscopic guidance, advance the delivery catheter over the guidewire. Advance cautiously, especially if resistance is felt. If excessive resistance is felt, at the physician's discretion, remove the delivery catheter and endoscope together.
4. Position the GORE® VIABIL® Short Wire Biliary Endoprosthesis across the target stricture using the radiopaque markers on the stent. These markers identify the proximal and distal ends of the loaded endoprosthesis. **The GORE® VIABIL® Short Wire Biliary Endoprosthesis should extend at least 2 cm proximal and distal to the margins of the stricture. Positioning should not result in excessive length into the duodenum.** If an endoprosthesis with transmural drainage holes is selected, the middle and hepatic end radiopaque rings demarcate the boundaries of the holed region. If transpapillary stent placement is desired, advance the catheter until the white edge of the distal end of the covered stent / containment line is visible just outside the papilla (approximately 1 cm recommended). This orientation must be maintained throughout the entire line-pull process of endoprosthesis delivery.
5. Once optimal endoprosthesis position is verified fluoroscopically and endoscopically, the endoprosthesis is ready to be deployed.
   Note: Should it become necessary to remove the GORE® VIABIL® Short Wire Biliary Endoprosthesis from the duct prior to deployment, you may withdraw the catheter with loaded endoprosthesis back into the endoscope working channel after the catheter is fully advanced into the bile duct.
6. Ensure the delivery catheter is straight coming out of the endoscope working channel.
7. Stabilize the delivery catheter at the entrance of the working channel of the endoscope. It is also important to stabilize the endoscope relative to the patient. This will minimize catheter movement during deployment and ensure accurate endoprosthesis positioning.
8. Untwist the screw-connector at the base of the deployment knob. Relax the elevator. While keeping the segment of the catheter outside the endoscope working channel straight, slowly pull the deployment knob away from the hub. The deployment line incorporates a double layer of line over the constrained endoprosthesis. Approximately 10-25 cm (depending on endoprosthesis length) of initial deployment line pull ("pre-deployment pull") is necessary to release the first layer of line from the catheter (hub to tip) constraining the endoprosthesis and before deployment release of the endoprosthesis from the delivery catheter begins. **Deployment of the endoprosthesis will occur from the tip of the delivery catheter toward the hub (hilar to duodenal).** Approximately 25-65 cm (depending on endoprosthesis length) of total deployment line pull is necessary for complete deployment of the endoprosthesis. Continue to pull deployment line until it exits the deployment catheter. If deployed as instructed, the endoprosthesis will not appreciably foreshorten.
   Note: Once deployment has started, repositioning of the endoprosthesis should not be attempted.
   Note: To fully deploy the device to its labeled length, maintain constant position of the delivery catheter during deployment. Note that pushing forward on the catheter during deployment may result in a device length shorter than the labeled length.
   Note: The device will not be longer or a larger diameter than what is labeled.
9. Following deployment of the endoprosthesis, maintain position of the guidewire across the treated stricture. Carefully withdraw the delivery catheter through the lumen of the endoprosthesis and remove through the working channel of the endoscope. Moderate resistance may be felt when the distal tip is withdrawn into the endoscope working channel. Excessive or abrupt force during catheter removal may damage the endoprosthesis, or delivery catheter. If excessive resistance is felt when withdrawing delivery catheter through lumen of endoprosthesis, it is recommended to wait a few minutes to allow the endoprosthesis to expand further allowing ease of removal.

INSTRUCTIONS FOR USE *(continued)*

10. Using standard cholangiographic procedures, the position and patency of the endoprosthesis should be verified. If the stricture does not allow the endoprosthesis to immediately expand to its full diameter, it is possible that it will further expand over the course of several days. Balloon inflations may be used to expand the endoprosthesis. The balloon diameter selected for this purpose should be less than the nominal diameter of the GORE® VIABIL® Short Wire Biliary Endoprosthesis used.
11. It is acceptable to place multiple devices to achieve complete coverage beyond a stricture (i.e., greater than or equal to 2 cm). Devices need to be overlapped by at least 1 cm. It is recommended that only devices of the same diameter be overlapped. Even though the order of placement may be dependent on the patient's anatomy and physician's judgment, it is recommended that the device closest to the duodenum or most downstream device is placed first.

D. Post-Deployment

1. When clinically appropriate, remove any guidewires or catheters and then the endoscope.

STERILIZATION

The GORE® VIABIL® Short Wire Biliary Endoprosthesis is supplied STERILE. The GORE® VIABIL® Short Wire Biliary Endoprosthesis should not be resterilized.

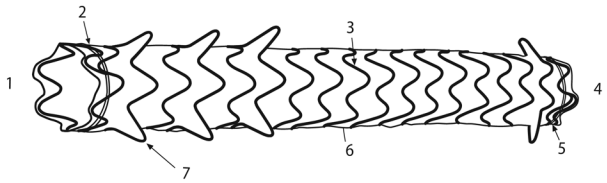


Figure 1: GORE® VIABIL® Short Wire Biliary Endoprosthesis - Fully Covered:
1. HEPATIC END, 2. Radiopaque Ring, 3. Nitinol Stent, 4. DUODENAL END, 5. Radiopaque Ring, 6. ePTFE / FEP Lining, 7. Covered Anchoring Fins

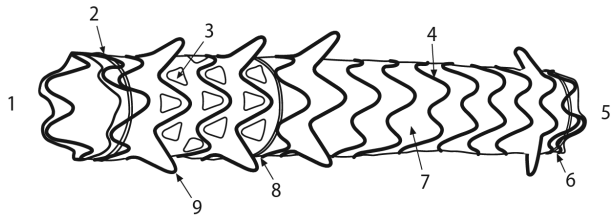


Figure 2: GORE® VIABIL® Short Wire Biliary Endoprosthesis with Transmural Drainage Holes:
1. HEPATIC END, 2. Radiopaque Ring, 3. Transmural Drainage Holes, 4. Nitinol Stent, 5. DUODENAL END, 6. Radiopaque Ring, 7. ePTFE / FEP Lining, 8. Radiopaque Ring, 9. Covered Anchoring Fins

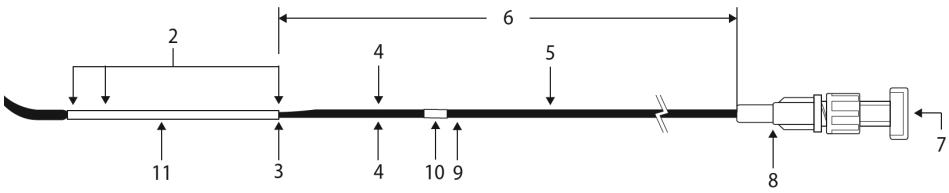


Figure 3: GORE® VIABIL® Short Wire Biliary Endoprosthesis Endoscopic Delivery Catheter System:
1. Curved Tapered Tip, 2. Radiopaque Marker Rings, 3. Proximal Radiopaque Catheter Marker, 4. 8.5 Fr, 5. Catheter Shaft, 6. Working Length 200 cm
7. Deployment Knob, 8. Hub, 9. Guidewire Exit Port, 10. Guidewire Exit Port Indicator, 11. Biliary Endoprosthesis

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